

Claims

1. A method of making a dry powder composition for pulmonary inhalation, the method comprising spray drying a pharmaceutically active agent to produce active particles, wherein the active agent is spray dried using a spray drier comprising a means for producing droplets moving at a controlled velocity.

2. A method as claimed in claim 1, wherein the velocity of droplets at 5mm from their point of generation is less than 20m/s.

10 3. A method as claimed in claim 1 or 2, wherein the spray drier comprises an ultrasonic nebuliser.

15 4. A method as claimed in claim 3, wherein the output of each single nebuliser unit is greater than 5cc/min.

5. A method as claimed in claim 4, wherein the output of each single nebuliser unit is greater than 10cc/min.

20 6. A method as claimed in any one of the preceding claims, wherein 90% of the resulting dried particles have a size of less than 5 μ m, as measured by laser diffraction.

25 7. A method as claimed in claim 6, wherein 90% of the resulting dried particles have a size of less than 2.5 μ m, as measured by laser diffraction.

8. A method as claimed in any one of the preceding claims, wherein the active agent is co-spray dried with a force control agent.

30 9. A method as claimed in claim 8, wherein the force control agent is an amino acid, a phospholipid or a metal stearate.

10. A method as claimed in claim 9, wherein the force control agent is one or more of leucine, lysine and cysteine.

11. A method as claimed in any one of claims 8-10, wherein a blend of active agent and force control agent is spray dried, and the blend is a solution.

12. A method as claimed in any one of claims 8-11, wherein a blend of active agent and force control agent is spray dried, and the blend is a suspension.

10 13. A method as claimed in claim 11 or 12, wherein the active agent and force control agent are spray dried from an aqueous solution or suspension.

14. A method as claimed in any one of the preceding claims, wherein the active agent is co-spray dried with a force control agent to produce dry particles comprising up to 20% w/w force control agent.

15. A method as claimed in any one of the preceding claims, wherein the method comprises adjusting the moisture content of the spray dried particles.

20 16. A dry powder composition for pulmonary inhalation, wherein the composition is spray dried and comprises particles of a pharmaceutically active material having a force control agent concentrated on the surfaces of the particles.

17. A composition as claimed in claim 16, wherein the composition comprises 25 no more than 20% w/w of an additive which acts as a force control agent.

18. A composition as claimed in either of claims 16 and 17, wherein at least 90% of the particles in the composition have a size of less than 5 μ m, as measured by laser diffraction.

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19. A composition as claimed in any one of claims 16-18, wherein the composition has a fine particle fraction of at least 40%, at least 50%, at least 60% or at least 70%.

20. A composition as claimed in any one of claims 16-19, wherein the composition has a density greater than 0.1g/cc.
- 5 21. A composition as claimed in any one of claims 16-20, wherein the particles are prepared using a method as claimed in any one of claims 1-15.